SOP 07 A



Medical college and Hospital

SOP code: SOP 07A/ V2.1

Initial Full Board Review of New Research Study Protocols

Effective Date: 15.11.2019

Title:

Initial Full Board Review of New Research Study Protocols

Note:

New annexure no 2 is added after approval of SMVMCH-EC members. It is

amended and will be effective from 15.11.2019

Study Assessment Form to be used by the Primary Reviewer Annexure 2-(Annexure 02/SOP/7A/V2.1)

Annexure 2: AX 02/SOP 7A/V2.1

Study Assessment Form to be used by the Primary Reviewer

	IE	C code number of Proto	ocol:	Date (DD/MM/YY	7):		
	Pr	otocol Title:				100	
	Pr	Principal Investigator:					
					THE CLASSIC STREET		
	De	epartment:					
	No	o. of Participants:		No. of Study site (s):			
		rk and comment on w	hatever items are				
S. N	No	Item		Comn	nents (if any)		
1.		Objectives of the Study	/				
		☐ clear ☐	unclear				
2		Need for Human Partic	ripants				
		Yes N	No				
3		Methodology: (commo	ent on sample				
		size)					
		□ clear □	lunclear				
			diferent				
4 a	1.	Background Informati	on and Data				
		Sufficient	Insufficient				
4 b).	Risks and Benefits As	sessment				
		Acceptable	Unacceptable				
4 c	.	Inclusion Criteria					
		Appropriate	Inappropriate				
4 d	i.	Exclusion Criteria					
		Appropriate	Inappropriate		keleta dan berse		

SOP 07 A	MANAKULA VINAYAGAR Medical college and Hospital	
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S. No Item Comments (if any) 4 e. Discontinuation and Withdrawal Criteria Appropriate Inappropriate \square NA Involvement of Vulnerable Participants: 5 Yes No [Control Arms (placebo, if any) 6 Yes No \square NA \square Contents of the Informed Consent Document: unclear clear 7 Language of the Informed Consent Document: unclear clear 8 Inducement for Participation 9 Unlikely | Likely | Provision for Compensation for Participation Appropriate inappropriate 10 NA NA Provision for Treatment for Study-Related Injuries Appropriate inappropriate 11 \square NA

Any other comments:

Reviewer's Signature with date:

SOP 07 A



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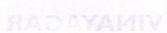
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	Name	Designation	Signature
	Dr. Vimal. M	Member	gain at
Prepared	Dr. Nishanthi. A	Member	d. Nishelli
n : 1	Dr. R. N. Kagne	Member Secretary	7
Reviewed	Dr. Amol Dongre	Member	AD 18 m/15
Approved	Dr. T. Thiagarajan	Chairman	h
Issued	Dr. D. Rajagovindan	Director, SMVMCH	A.

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Date: (5 11.2019

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